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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,813	09/11/2003	Mark P. Warchol	00479/2/US	5252

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GLOBAL PATENT DEPARTMENT
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EXAMINER	
HAND, MELANIE JO	

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 03/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/659,813	WARCHOL ET AL.	
	Examiner	Art Unit	
	Melanie J. Hand	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-36 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-36 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 11 September 2003 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 9/29/03.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Priority

Acknowledgment is made of applicant's claim for priority under copending Provisional Application No. 60/413,959 filed on September 26, 2002.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on September 29, 2003 was filed after the mailing date of the Application on September 11, 2003. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-28, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Voges (U.S. Patent No. 5,894,841) in view of Booth et al (U.S. Patent No. 4,952,212).

With respect to **Claims 1,2,9,21-24,27,35,36:** Voges teaches a dispenser 1 capable of delivering corticosteroids that are used in eye medicaments. Voges teaches that the medicament is delivered in droplet form by means of a thermal resistor bubble jet device 14. Device 14 is energized via a battery 17 controlled by on-off control switch 18 accessible by a user. When switch 18 is turned on, device 14 delivers liquid from cartridge 10 as a spray directed outwardly from the dispenser via nozzle 25. Voges teaches a droplet diameter of 150 microns, and since Voges also teaches that the rate is controlled by programmed circuit 16 according to predetermined criteria (Col. 6, lines 49-51), the device of Voges is capable of delivering an amount of medicament no greater than 50 μL. Since Voges teaches mouthpiece 5 for engaging the mouth area of a user that surrounds droplet ejection orifices 15 and also teaches that the agent delivered is a corticosteroid which is a type of drug used in eye medication, Examiner is concluding that mouthpiece 5 is also suitable as a standoff for positioning dispenser 1 so as to dispense medication directly into the eye in spray form.

Voges does not teach a rate of issuance less than 5 μL/sec. Booth teaches a metered dose of 20 μL and below is sprayed as a metered dose, and that no more than 20 μL is provided to the spray nozzle, therefore, the rate assuming a delivery time interval of at least one second would be at most 20 μL/sec. Booth teaches that this amount reduces waste, as typically only 5-7 μL reaches the eye, therefore it would be obvious to one of ordinary skill in the art to modify the amount dispensed by the device taught by Voges to be no more than 20 μL with a rate of issuance of at most 20 μL/sec as taught by Booth.

With respect to **Claims 3-6:** Voges teaches one or more touch pad switches 26 which condition control means 16 which in turn controls bubble jet orifices 15 of device 14 and/or which controls the repetition rate of device 14 thus controlling the number of droplets delivered in a unit of time. (Col. 10, lines 66,67, Col. 11, lines 1-5). Voges teaches that control circuit 26 comprises a single line LCD. (Col. 11, lines 54-56)

With respect to **Claim 7:** Vogel teaches that cartridge 10 is disposable or replaceable and that container 10 is adaptable for fluid communication with inlet 12. (Fig. 2) (Col. 6, lines 37-40)

With respect to **Claim 10:** As can best be seen in Fig. 5, Voges teaches that bubble jet device 14 is located directly behind droplet delivery orifices 15.

With respect to **Claim 11:** As can best be seen in Figs. 1 and 2, mouthpiece 5 is disposed around delivery orifices 15.

With respect to **Claim 12:** Since Voges teaches that the rate of droplets per unit time can be controlled by the user via touch pad switches 26, the time interval can also be controlled so as to be no more than one second.

With respect to **Claims 13-15:** Voges does not teach particular time intervals for the dispensing of droplets, however since device 14 is capable of being controlled so as to not emit medicament for more than one second, the time intervals of 0.5, 0.25 and 0.1 seconds as claimed in claims 13-15 respectively are considered optimizations of the parameter of time.

With respect to **Claim 16:** Voges does not teach a drug in dispersed form. Booth teaches an ocular treatment solution comprising fluorescein, which is liquid but insoluble in water and therefore creates0 a dispersion when mixed with water. Fluorescein is known in the art as a diagnostic as taught by Booth ('212, Col. 2, line 39), which is a useful compound for diagnosing diseases such as diabetic retinopathy, a disease for which Booth teaches this solution is suitable ('212, Col. 2, lines 42-47), therefore it would be obvious to one of ordinary skill in the art to add an insoluble diagnostic to the solution taught by Voges as taught by Booth.

With respect to **Claim 17:** Voges teaches that the spray of medicament comprises corticosteroid in droplet form in a water solvent, thus the drug is in dissolved form. Voges specifically teaches nicotine in water, however since Voges teaches that corticosteroid is also a suitable medicament, it is concluded herein that the corticosteroid is capable of being accompanied by a water solvent.

With respect to **Claims 18-20:** Voges does not teach a particular percentage for presence by weight of said corticosteroid. Booth teaches an ocular treatment solution comprising corticosteroid and an organic diluent. Booth teaches examples of the solution of the invention wherein in each, the ophthalmically active substance is present in 4% by weight. Booth is teaching this as the suitable proportion for said active substance. Booth teaches that this solution can effectively deliver pharmaceutical compounds to the eye, therefore it would be obvious to one of ordinary skill in the art to modify the proportion by weight of the corticosteroid in the solution taught by Voges to employ the conventionally utilized amount taught by Booth with a reasonable expectation of success. With respect to claim 19, since applicant has not assigned criticality to having a solution comprising an active substance in an amount less than

1% or less than 2% by weight versus less than 5% by weight, Examiner is regarding the combined teaching of Voges and Booth as prior art also rendering Claims 19 and 20 unpatentable.

With respect to **Claim 25:** Voges teaches the use of corticosteroids, which are anti-inflammatory substances and therefore are capable of treating chronic conjunctivitis.

With respect to **Claim 26:** Voges does not teach a substance in said solution in dispenser 1 that would treat any of the diseases or disorders set forth in the group of items in Claim 26. Booth teaches a solution that contains an active drug substance for treatment of diabetic retinopathy. Since Voges and Booth both teach ophthalmically active substances in water solvents, the solution of Booth is considered herein to be an alternative method for treating the eye of a disorder or disease. In the instant case substitution of equivalent methods requires no express motivation, as long as the prior art recognizes equivalency, *In re Fount* 213 USPQ 532 (CCPA 1982); *In re Siebentritt* 152 USPQ 618 (CCPA 1967); *Graver Tank & Mfg. Co. Inc. v. Linde Air Products Co.* 85 USPQ 328 (USSC 1950).

With respect to **Claim 28:** Voges does not teach any of the substances in the group of items in claim 28. Booth teaches prednisolone as a specie of corticosteroid to treat inflammatory conditions of the eye ('212, Col. 2, lines 26,27), therefore since Voges teaches a solution with corticosteroid, it would be obvious to one of ordinary skill in the art modify the solution taught by Voges so as to contain prednisolone as the conventionally used specie of corticosteroid.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Voges ('841) in view of Booth et al ('212) as applied to claims 1-28, 35 and 36 above, and further in view of Cornish (U.S. Patent No. 6,033,389).

With respect to **Claim 8:** The combined teaching of Voges and Booth does not teach a standoff from dispenser 1 in the form of a cup having a rim contoured to engage a circumocular surface. Cornish teaches an eye medicament dispensing device 10 that expels medicament along with a stream of air through mouth 20 having orifice 36. (Fig. 1) Device 10 has eye cup structure 40 linked to container 12 by an intermediate tube member 26. ('389, Col. 3, lines 34-42) Cornish teaches that this structure acts as a guide to ensure that the medicament is channeled properly toward cornea 68 and prevents end portion 32 from touching cornea 68 ('389, Col. 4, lines 30-35), therefore it would be obvious to one of ordinary skill in the art to modify the dispenser of the combined teaching of Voges and Booth by adding a tube attachment configured to attach to an eyecup as taught by Cornish.

Claims 29-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Voges ('841) in view of Booth et al ('212) as applied to claims 1-28, 35 and 36 above, and further in view of Laibovitz et al (U.S. Patent No. 6,159,188).

With respect to **Claims 29-31,34:** The combined teaching of Voges and Booth does not teach that said solution contains a $PGF_{2\alpha}$ derivative. Laibovitz et al teaches an apparatus for delivery of microquantities suited for ophthalmic applications (see Abstract). Laibovitz teaches a solution that may contain unoprostone or latanoprost as a prostaglandin. ('188, Col. 49, lines 54-56) Laibovitz teaches that prostaglandins are commonly used ophthalmic fluids ('188, Col. 11, lines

47-56) and are compatible with water therefore it would be obvious to one of ordinary skill in the art to substitute corticosteroid in the solution taught by the combined teaching of Voges and Booth with another commonly used ophthalmic fluid as taught by Laibovitz.

With respect to **Claims 32 and 33:** Voges does not teach that said solution comprises a beta-adrenergic blocking agent. Laibovitz teaches a solution comprising timolol ('188, Col. 49, lines 46-48), and that such a drug is commonly used in ophthalmic fluids ('188, Col. 11, lines 47-56), therefore it would be obvious to one of ordinary skill in the art to modify the solution of Voges so as to compromise timolol as taught by Laibovitz.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melanie J Hand

Examiner
Art Unit 3761

MJH

NA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER